

I. Status of The Application

The Examiner restricted the application into the following six separate inventions:

I. Claims 1-6 (Group I), directed generally to a protein, composition, and a kit classified in class 530, subclasses 300 and 350; class 424, subclasses 185.1 and 193.1; class 514, subclass 21.

II. Claims 7-9 (Group II), directed generally to an antibody and a kit, classified in class 530, subclasses 387.9 and 391.3.

III. Claim 10 (Group III), drawn generally to a method of purifying protein using antibody, classified in class 530, subclass 413.

IV. Claims 11-17 (Group IV), drawn generally to a nucleic acid, vector, host cell and kit, classified in classes 536, subclasses 23.5, 24.3 and 24.33; class 435, subclasses 320.1, 325, 348, 352, 366, 252.1 and 255.1.

V. Claim 18 (Group V), drawn generally to a method of modulating the physiology or development of a cell, classified in class 435, subclasses 375 and 377.

VI. Claims 19 and 20 (Group VI), drawn generally to a method of modulating the physiology or development of a cell, classified in class 435 and subclasses 69.1 and 375.

II. The Invention

The present invention relates generally to compositions and methods of use of 499E9, a polypeptide which exhibits structural motifs that are characteristic of a member of the TNF ligand family.

III. The Restriction Requirement

Applicants provisionally elect, with traverse, Group IV (claims 11-17, drawn generally to a nucleic acid, vector, host cell and kit, classified in classes 536, subclasses 23.5, 24.3 and 24.33; class 435, subclasses 320.1, 325, 348, 352, 366, 252.1 and 255.1). Applicants select, with traverse, an embodiment from Group IV, Claim 11(xi), which is directed generally to a natural full length coding sequence of an isolated or recombinant nucleic acid encoding a protein or polypeptide of Claim 1. Applicants also select, with traverse, a species, a cell of Claim 12, and an embodiment of said species, a human cell of Claim 13.

Applicants understand that there are two criteria for a proper Restriction Requirement according to MPEP §803:

- (1) the invention must be independent or distinct as claimed, and

(2) there must be a serious burden on the Examiner if the restriction is not required.

Moreover,

5 "If the search and examination of the entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions."

Also,

10 "Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement."

Applicants submit that the restriction requirement is improper because the claims are so closely related that they should remain in the same application to preserve unity of invention, and that examination of the groups together
15 would not present a serious burden to the Examiner. The claims of the invention relate to a single subject matter. Restriction must then be based upon their distinctness, as claimed. According to MPEP §802.01, this means that they are capable of separate manufacture, use or sale, and are patentable over each other. The Examiner has directed comments to the question of whether the
20 invention(s) is/are independent and distinct, however, the Examiner has not addressed the question of burden. Search of class 536 or class 435, as required in the elected group, overlaps with classes to be searched for groups V and VI which will be added by rejoinder. Search of groups I, II, and III all require search of a single class (i.e., class 530).

25 The Examiner has concluded that a restriction is proper without addressing both the issue of independence/distinctness and the issue of burdensomeness. Applicants respectfully request reconsideration of the latter determination in view of the significant overlap of the search required. Applicants therefore, respectfully request reconsideration and withdrawal of the
30 Restriction Requirement.

Furthermore, according to MPEP §821.04,

35 "if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined."

The MPEP at §821.04 further instructs that,

". . . applicants are encouraged to present such process claims . . . in the application at an early stage of prosecution."